PROCEDURAL GUIDANCE FOR SELECTED STRATEGIES AND INTERVENTIONS FOR COMMUNITY BASED ORGANIZATIONS FUNDED UNDER PROGRAM ANNOUNCEMENT 04064

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Since the early days of the HIV/AIDS epidemic the Centers for Disease Control and Prevention (CDC) has worked with its partners to prevent the acquisition and transmission of HIV. Through the tireless work of dedicated frontline staff, medical professionals, and researchers, a number of successes have been realized. Behavioral interventions and medical advances have led to improvements in survival and quality of life for many people living with HIV and to decreases in the number of new infections. However, after years of declining infection rates, the number of new infections began to stabilize at about 40,000 per year in the early 1990's. Two concerning trends have emerged recently. First, data indicate that there has been an increase in behaviors that put people at risk of infection with HIV. Second, syphilis cases increased for the second year in 2002, reversing a decade of decline. In addition, trends in HIV diagnoses in 25 states with HIV reporting since 1993 show a rise for the first time in over a decade. It remains to be seen if this trend is due to increased testing or to an increase in the number of new infections. In the third decade of the epidemic, the HIV/AIDS prevention community is facing increasing challenges to which we must respond.

The purpose of the *Guidance* is to provide community-based organizations (CBOs) with sufficient information about the services described in order to determine activities for which they will request funding under Program Announcement 04064. To receive funding under CDC's Program Announcement 04064, organizations must propose in their applications to implement interventions from the *Guidance* appropriate for their respective target populations and their organization's capacity to conduct them. Interventions that are not in the *Guidance* will not be funded.

The information contained in this document should assist agencies in creating a plan for delivery of the service. It is not intended to provide the level of operational detail necessary to fully design and implement the programs described. CDC will provide intervention materials, and

training and technical assistance related to the interventions and services described in this *Guidance* to ensure that successful applicants understanding of the appropriate procedures for delivery and monitoring of the services to be provided. Many of these materials are already available (www.effectiveinterventions.org) and others will be available in the coming months.

In April 2003, CDC announced a refocusing of its prevention efforts to meet these challenges. *Advancing HIV Prevention: New Strategies for a Changing Epidemic* aims to support the prevention work of the past two decades while using emerging technologies (e.g., rapid testing, new interventions designed to meet the prevention needs of people living with HIV (PLWH) to expand and strengthen our efforts. The strategies identified to help achieve this goal focus directly on reducing barriers to early diagnosis; improving referral to state-of-the-art preventions services, medical care, and treatment; and ensuring that prevention programs are in place to assist people living with HIV. This *Guidance* provides direction for the design of community-based programs that address the strategies of AHP and meet the needs of communities.

In Program Announcement 04064, CDC will continue to support interventions for people at high risk for HIV infections and will also fund interventions in support of AHP.

The Procedural Guidance

The *Procedural Guidance* was developed as a means of bringing the best available science on HIV prevention to organizations that are working to meet the prevention needs of their communities. Although CDC recognizes the contribution of programs that have not yet received rigorous evaluation, the redoubling of prevention efforts has led to the need to place a premium on programs with evidence of effectiveness for reducing behaviors associated with the transmission of HIV. Through a thorough review of the literature on HIV prevention interventions, and with contributions from researchers and program experts, this *Guidance* is presented as a means to bring consistency to, and support for, the delivery of evidence-based HIV prevention interventions and strategies.

The *Guidance* is divided into 3 sections, which match the 3 major activities that will be funded through Program Announcement #04064. Section 1 describes procedures for targeted outreach and health education/risk reduction (HE/RR) for high-risk individuals. Section 2 describes procedures for targeted outreach and counseling, testing, and referral (CTR) services for high-risk individuals. Section 3 describes procedures for prevention interventions for people living with HIV and their partners of negative or unknown serostatus. Section 3 also includes interventions for persons at very high risk for HIV infection, defined as someone who, within the past 6 months, has had unprotected sex with a person who is living with HIV; unprotected sex in exchange for money or sex; multiple (greater than 5) or anonymous unprotected sex or needle-sharing partners; or has been diagnosed with a sexually transmitted disease.

This *Guidance*, along with intervention kits produced by the Replicating Effective Programs (REP) project and disseminated by the Diffusion of Effective Behavioral Interventions (DEBI) project represent the best currently available science related to HIV prevention.

The REP project translates HIV prevention interventions that have been shown to be effective at reducing risk behaviors into everyday language and puts them into user-friendly packages of

materials. REP interventions are available on the web at http://www.cdc.gov/hiv/projects/rep/default.htm.

The DEBI project is a national-level strategy to provide training and on-going technical assistance on selected evidence-based HIV/STD interventions to state and community program staff. DEBI interventions are available on the web at http://www.effectiveinterventions.org.

These evidence-based interventions will be supported by CDC, and organizations interested in partnering with CDC can choose from these interventions to create a plan for services that will meet the needs of their clients.

Not all agencies will have the capacity to deliver the interventions and services as they are described in this *Guidance*. Those agencies that are interested in a particular strategy but are unable to address all aspects of that service should partner with complementary agencies that would bring additional skills to the collaboration.

How to use the *Guidance*

The *Procedural Guidance* provides direction for the design of prevention programs including recruitment strategies to promote counseling and testing, HE/RR, and other prevention services; counseling, testing and referral (CTR) strategies; and prevention interventions to meet the needs of PLWH, their partners, and other uninfected individuals at high risk for HIV. Each strategy or intervention is outlined using the following eight subheadings:

Description: Provides a brief description of the strategy and evidence of effectiveness.

Core Elements, Key Characteristics, and Procedures:

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which ~~it~~ the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy.

Procedures describe the activities that make up the content of the program and provide direction to agencies or organizations regarding its implementation.

These features will be elaborated below in the description of adaptation and tailoring of interventions.

Resource Requirements: Discusses the ideal staffing patterns and materials needed for effective implementation of the intervention

Recruitment: Gives guidance on the recruitment activities that have been successful for the strategy or intervention described, and/or refers the reader to choose a strategy from the *Procedural Guidance for Recruitment* (included in this document) that is most appropriate for the organization or population.

Physical Setting and Characteristics: Describes the ideal setting or location for implementing the strategy or intervention described.

Necessary Policies and Standards: Discusses the policies which must be in place within an agency or organization to implement an intervention or strategy with respect to legal, ethical, and culturally appropriate guidelines.

Quality Assurance: Provides procedures for ensuring that the intervention or strategy is carried out with fidelity and with respect to the necessary policies and standards.

Monitoring and Evaluation: Describes data to be collected to ensure that the intervention or strategy is reaching the intended population and to determine effectiveness.

Adaptation and Tailoring

Interventions to prevent the acquisition of HIV (interventions directed toward people of negative or unknown serostatus) have received a great deal of attention from researchers and others interested in HIV prevention since transmission routes were identified in the early years of the epidemic. For this reason, the number of evidence-based interventions for this group has grown steadily, and interventions are now available for a variety of populations and settings. Interventions to reach individuals of negative or unknown HIV status at high risk for HIV infection can be found on the REP and DEBI websites listed above. As PLWH have been diagnosed earlier in their infection, and treatment advances have led to greater length and quality of life, the prevention needs of PLWH have begun to receive more attention. Currently, a number of science-based interventions are available to address the strategies of the AHP initiative. The need for additional, proven prevention-with-positive interventions is being addressed by the scientific community, with several interventions currently being evaluated.

While the investigators who designed these interventions have made every attempt in their research efforts to include the groups that are most impacted by the HIV/AIDS epidemic, no intervention study can be designed to demonstrate efficacy in every group at risk for transmission or acquisition of HIV. However, because the theories of behavior change upon which interventions are based are generalizable across a number of behaviors and populations, the interventions can be adapted and tailored to meet the specific needs of groups that were not part of the original research. While the core elements of an intervention cannot be changed, the key characteristics can be modified to suit the needs of the agency or target population.

Adaptation of an intervention or strategy implies that it is being delivered to a different population or in a different venue than the one in which efficacy was originally demonstrated. For example, the Popular Opinion Leader intervention was originally designed to reach gay men in bars, but was successfully adapted for use with African-American women in an urban housing

project. VOICES/VOCES was originally tested in sexually transmitted disease (STD) clinics but has been found to be appropriate when delivered to persons in drug treatment settings.

Tailoring, on the other hand, occurs when an intervention or strategy is changed to deliver a new message (for example, addressing condom use versus limiting the number of partners), at a new time (at a weekend retreat rather than over a series of weeks), or in a different manner (using verbal rather than written messages) than was originally described.

Adaptation involves changes in *who* receives an intervention and *where* it is delivered, while tailoring leads to changes in *when* it is delivered, *what* is addressed, and *how* the message is conveyed. Adaptation questions should be addressed before attempting to tailor the intervention or service. Adaptation must be addressed before tailoring because the population and the determinants that put persons at risk for HIV infection must be specified before messages and strategies can be tailored to address those risk determinants. In addition, identifying the venues in which the intervention is delivered may assist in determining how the intervention will be delivered. The strategies described in this *Guidance* can be adapted and tailored with a reasonable expectation of success if these variations are based on the demonstrated needs and special circumstances of the population to be addressed.

Adapting or tailoring of an intervention must come from an understanding of the population for which the intervention is intended and should take into account both culturally relevant factors for the group being served as well as thorough knowledge of the risk behaviors and risk determinants that place the population at risk for HIV infection. Providers cannot make the assumption that because an intervention will be delivered by a member of the target population, it will be appropriate for that population. Cultural identity does not necessarily lead to cultural competency. Information about risk behaviors and determinants can only be gathered with an appropriate formative evaluation of the target population.

Formative evaluation is a series of activities undertaken to furnish information that will guide the program adaptation, tailoring, and development process. Formative evaluation involves the identification of the risk determinants that were addressed in an evidence-based intervention and then determining if the new target population has these or similar risk determinants. For example, the SISTA intervention recognizes that African American women must negotiate with their male sexual partners to convince these partners to use condoms. If an organization wanted to adapt SISTA to Hispanic women, they would have to determine if negotiation with male sexual partners was also relevant for Hispanic women. If so, then SISTA may be appropriately adapted for Hispanic women.

Careful review of evidence-based behavioral interventions may also identify important mediators and moderators for achieving the effects of the intervention. *Mediators* are internal facilitators of risk-reduction skill acquisition. Self-efficacy (belief that one can change behavior), intentions (plan to change behavior), perceived peer norms (beliefs about peers' behavior), and outcome expectancy (belief about consequences of behavior change) are often identified as mediators for risk reduction. *Moderators* include external supports and barriers of risk-reduction skill acquisition. For example, Street Smart is an intervention for homeless and runaway adolescents, which is typically delivered in a runaway or homeless shelter. Because the youth are housed in

the shelter, access to the target population has been increased. Thus a moderator, access, has been addressed by taking the intervention to a site where homeless and runaway youth can be reached. When adapting an intervention for a new population it is necessary to determine whether the new target population has the same or similar mediators and moderators influencing risk-reduction behaviors as the original population.

To ensure the best chance of success for an intervention in any community, the needs of that community must be assessed and the goals of the intervention must be specified to ensure that they are in line with the needs and concerns of the target population. Following the steps of a formative evaluation can help an agency or organization to answer adaptation questions regarding to whom an intervention should be delivered, and changes in location that are necessary, as well as tailoring questions such as the most effective message and means of delivery, as well as the timing of the intervention. Steps of a formative evaluation include:

1) **Interviews** with community gatekeepers and stakeholders can be used to determine the feasibility of delivering an intervention in the context in which an agency or organization has targeted. Community gatekeepers are persons who can either facilitate or undermine implementation of an intervention in a particular community or venue as well as with a particular target population.

    For example, Popular Opinion Leader (POL) an intervention with men who have sex with men (MSM) suggests that owners of gay bars be interviewed prior to implementation of the intervention to ensure that the bar owners endorse the intervention, will allow the intervention to take place in their venue, and will support the intervention by encouraging bar employees to participate in the identification of POLs. Another example is the SISTA intervention, which has been delivered to women in county and city jails. The managers and guards of these facilities must be interviewed prior to implementation to ensure that they will allow the intervention into their facility.

    Another consideration is the need to ensure that the service is needed in the opinion of community gatekeepers and stakeholders.

    For example, when attempting to adapt and tailor the intervention Safety Counts, community gatekeepers and stakeholders may say “We already have street outreach, why do we need another intervention in our community for drug users?” Agency staff should then explain that Safety Counts is an intervention that actively recruits injection drug and cocaine users into prevention counseling, rapid testing, partner services, individual and group level interventions, prevention case management, medical services and family focused social events. Community gatekeepers and stakeholders must be informed that Safety Counts is a specific outreach method with specific goals and is not the typical outreach they may have experienced in their community in the past.

2) These interviews should be followed by **focus groups** of members of the target population to gain an understanding of the issues that are most important to and impact

most strongly upon the community. Before conducting the focus groups, the agency wishing to implement the evidence-based program should design the focus group questions. These questions should elicit information on HIV behavioral risk determinants, mediators for the risk behaviors, and moderators for the risk behaviors. If the risk determinants, mediators, and moderators are similar to those identified in the evidence-based program, then the evidence-based program may be appropriate for adaptation and tailoring. The focus groups must also discuss all the core elements of the original evidence-based intervention.

> For example, Mpowerment, an intervention for young gay men, has 5 core elements. These elements are 1) a core group of young gay men who help direct the project, 2) informal outreach to spread safer sex norms, 3) formal outreach to distribute safer sex materials into venues where young gay men can be accessed, 4) M-groups that build social and safer sex skills for young gay men, and 5) social marketing of norms and social events that reach young gay men who may not be reached by other components of the intervention.

Before implementing Mpowerment in a new community, focus groups should be held to determine if each of these core elements of the evidence-based program are feasible and appropriate for the new target population and venues. *Feasibility* includes human and fiscal resources as well as the level of skill attainment agency staff will need to implement the evidence-based intervention. *Appropriate* includes cultural and community values, gender, language, and age-related considerations. Several focus groups may be needed to explore HIV risk determinants in the target population and determine if they match the risk determinants in the evidence-based model. Several more focus groups may be needed to explore each core element of the original evidence-based model intervention to assess the potential of implementing these core elements with a new population or in a new venue.

3) The revised intervention should be based upon a **logic model.** The logic model is often displayed in a flow chart or table to portray the sequence of steps leading to expected intervention outcomes. A logic model is a program plan that links an evidence-based problem statement to intervention activities that address the problem statement. These intervention activities must then be linked to measurable intervention outcomes that address the problem statement and demonstrate reduced HIV risk. The logic model should be based on an evidence-based problem statement. The implementing agency should have epidemiological or other evidence that the target population is at risk for HIV infection, should understand the risk determinants for the population, and should document that the problem addressed in the original evidence-based intervention research and the problem in the new target population are similar. The logic model should identify inputs for each core element of the intervention. This means that the implementing agency should identify all the resources necessary to deliver an evidence-based intervention. Resources include human capital (employees, managers, and volunteers), supplies, venue costs, travel costs, incentives, and materials development. These inputs should be calculated for each planned core element. The logic modeling process should

review and consider carefully the behavioral outcomes that were obtained in the original research of the evidence-based intervention. Consideration should be given to the intensity and dosage of intervention activities that must be delivered to ensure that the adapted and tailored program makes every attempt to obtain or surpass the behavioral outcomes that were obtained in the original evidence-based intervention research.

> For example, Street Smart was able to increase condom use with homeless and runaway adolescents with 8 intervention sessions. If the implementing agency plans to obtain similar outcomes in their adapted and tailored program, they must be willing and able to provide a similar dosage (8 sessions) to their target population.

The logic model should fully describe and operationalize the core elements of an intervention or strategy and how these activities work together to prevent HIV. All intervention activities, based on the core elements of the intervention, should address the problem statement and be linked to clearly stated and planned outcomes.

4) **Pre-testing** of the intervention materials with an appropriate community advisory board can help to ensure that they are culturally competent and responsive to the needs of the target population. Pre-testing materials should cover a range of considerations including reading level of the target population, community values and norms, and attractiveness of the intervention materials. Health messages and intervention activities should be pre-tested to determine if instructions and messages are understood and retained by the new target audience.

5) **Pilot testing** of the revised intervention with a small subgroup of the population gives an indication of the usefulness of the adapted or tailored intervention. Pilot testing can be divided up into small pilots of each core element and then a pilot can be conducted of the entire intervention including all core elements. This strategy works best for individual or group level interventions.

> For example in the SISTA intervention, one group level session addresses gender and ethnic pride for African American women. If the intervention is adapted for Hispanic women, this session will need to be adapted for Hispanic women and then pre-tested with a group of Hispanic women before the intervention is implemented in a larger venue by the implementing organization.

Community-level interventions are very difficult to pilot as a full intervention. However, core elements of community-level interventions can be piloted. For example, in the PROMISE intervention, role model stories are distributed by a group of peer advocates to members of the target audience. Before distributing multiple role model stories in the community, the agency that is adapting and tailoring PROMISE should consider piloting the process with a small group of peer advocates that distribute just one role model story. This piloting will help the agency decide on how best to implement the adapted and tailored intervention on a larger scale.

Cultural Competence

Individuals and groups vary considerably by ethnicity, gender, age, sexual orientation, and language, and their experiences may result in cultural orientations that are consistent with these variations. It is important that providers consider the meaning of such cultural variations in the implementation and delivery of programs and services. Culturally competent programs and services result from acknowledging and responding appropriately to the health needs of persons within the context of their diverse cultural experiences.

In 2001, the Office of Minority Health (OMH) in the Department of Health and Human Services published a set of national standards for delivering culturally and linguistically appropriate services (CLAS). OMH began by defining cultural competence as

> "A set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals that enables effective work in cross-cultural situations. *Culture* refers to integrated patterns of human behavior that include the language, thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups. *Competence* implies having the capacity to function effectively as an individual and an organization within the context of the cultural beliefs, behaviors, and needs presented by consumers and their communities."

In order to become culturally competent, providers must value diversity, understand their cultural biases, be conscious of the dynamics that occur when cultures interact, internalize cultural knowledge, and develop adaptations to diversity. The OMH report offers the following standards as the basis for developing and measuring culturally and linguistically competent health programs and services. Organizations should:

1) Ensure that clients/consumers receive from all staff members effective, understandable, and respectful care that is provided in a manner compatible with their cultural beliefs and practices and preferred language;

2) Implement strategies to recruit, retain, and promote at all levels of the organization a diverse staff and leadership that are representative of the demographic characteristics of the service area;

3) Ensure that staff at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery;

4) Offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each client/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation;

5) Provide to clients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services;

6) Ensure the competence of language assistance provided to limited English proficient clients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the client/consumer);

7) Make available easily understood, client-related materials and post signage in the languages of the commonly encountered groups and/or groups represented within the service area;

8) Develop, implement, and promote a written strategic plan that outlines clear goals, policies, operational plans, and management accountability/oversight mechanisms to provide culturally and linguistically appropriate services;

9) Conduct initial and ongoing organizational self-assessments of CLAS-related activities and are encouraged to integrate cultural and linguistic competence-related measures into their internal audits, performance improvement programs, patient satisfaction assessments, and outcomes-based evaluations;

10) Ensure that data on the individual client's/consumer's race, ethnicity, and spoken and written language are collected in health records, integrated into the organization's management information systems, and periodically updated;

11) Maintain a current demographic cultural and epidemiological profile of the community as well as a needs assessment to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area (the HIV prevention community plan and other sources of relevant information);

12) Develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and client/consumer involvement in designing and implementing CLAS-related activities;

13) Ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by clients/consumers;

14) Regularly make available to the public, information about their progress and successful innovations in implementing the CLAS standards and to provide public notice in their communities about the availability of this information.

The interventions and strategies outlined in this document are presented as best practice models that can guide the services of an organization or agency that delivers services under the recommendations of *Advancing HIV Prevention.* As always, CDC relies upon its partners in the community to deliver effective, culturally relevant services to fight HIV, and will work with these partners to adapt and tailor the interventions in this guidance and in the REP and DEBI programs to meet the needs of the people they serve. The goals of this new initiative are to increase the number of PLWH who know their HIV status and to provide them and people at

high risk of HIV infection with the best available tools to stay healthy and reduce transmission of HIV.

Key Articles and Resources

http://www.cdc.gov/hiv/partners/ahp.htm

CDC. Advancing HIV Prevention: New Strategies for a Changing Epidemic. MMWR 2003; 52:329-332

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